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### ***Clinical Trials and Venture Tribulations: Stem Cell Research and the Making of Vietnamese Bio-entrepreneurs***

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#### **Abstract**

The article is concerned with biomedical technologies and the entrepreneurial ways through which these vital technologies come to life. Focusing on stem cell ‘clinical trials’ conducted in hospitals in Việt Nam, it traces the processes through which tentative experiments and uncertain results are being translated into commercial ventures. It pays particular attention to the complex institutional settings and collaborative engagements through which biomedical enterprise and markets come to be instituted. Of particular concern are network partnerships involving public bodies, policy makers and private business interests that facilitate the process of turning clinical experiments into vetted therapies for the healthcare marketplace. The article contributes to anthropological reflections on emerging bioscience economic formations that are widely termed as ‘bioeconomies’. It does so, by reorienting the analytical gaze away from understandings of economic value as inherently rooted in biological substances that hold a future promise of cure, towards ongoing processes of assembling biomedical entrepreneurial networks and turning biotechnical matters into commodities.

**Keywords:** stem cells; clinical trials; science entrepreneurship; market-making; networks; Vietnam

#### **Main Text**

In recent decades, there has been a growing interest in, and expectations for, the development of a global biotechnology industry. Stem cell science, which offers the prospect for developing treatments for severe and often fatal conditions by harnessing the regenerative powers of the cell, has been seized upon by governments and business interests

around the world as a particularly promising area of investment. The economic potential of stem cell technologies has been of intense interest not only to policy makers and venture capitalists but also to social scientists. Anthropologists and science studies scholars have become concerned with the increasing entanglement of contemporary life sciences and economic processes, a relation often summarised under the term 'bioeconomy' (Birch and Tyfield, 2012; Cooper, 2008a; Petersen and Krisjansen, 2015; Rajan, 2006; Rose, 2007; Waldby and Mitchell, 2006). Despite a wealth of reflections on 'bioeconomy' there is still little known about the actual ways in which biomedical innovation is produced and translated into commercial applications, and how science-based industries and markets come to life. The current article addresses such gaps in our knowledge by studying in ethnographic ways the scientific and social practices through which stem cell commercial applications and ventures take shape. Focusing on stem cell 'clinical trials' conducted in Vietnamese hospitals, the article considers the process through which tentative experiments and uncertain results are being turned into commodities for the healthcare marketplace, highlighting the complex institutional settings and collaborative engagements involved in this transformative process. Experiments conducted in public hospitals in the capital Hà Nội under the auspices of health departments and sponsorship by biotech firms provide ample scope for detailing such complex collaborative flows.

This first ethnographic account on stem cell practices in Việt Nam provides an interesting case through which to consider the rise of a global biotechnology industry and its local variations, a global-local relation theme that has been recurrent in anthropological discussions of contemporary biotechnology (Ong & Collier 2005; Sleeboom-Faulkner 2014). The emergence of bioscience economic formations in Asian settings has been a key area of focus for such discussions (Ong & Chen 2010; Rajan 2010; Sleeboom-Faulkner 2011). The rise

of competitive bioindustries in Asia and their often hazardous laissez-faire approach to stem cell experimentation and science regulation have been key points of concern for many studies. China, India and Singapore in particular have served as cases for considering the challenges life science practices, and their perilous coupling with fiercely competitive economics and potent Asian nationalisms, pose to science ethics, citizenship and democratic governance (Ong 2006; Ong & Chen 2010; Salter 2008; Song 2011). In China and Singapore, Ong observes (2006), respective governments have sought to build competitive bioindustries by carving out *zones of exception* that operate outside national science and market regulations, hence engineering areas for scientific and political experimentation. Issues of 'biopolitics', and more particularly the exercise of state power over the realm of life and biology, have been extensively discussed in studies of biotechnology in Asia and elsewhere in the world (cf. Rose 2007). What remains less studied is the intricate entanglements of state, public and private actors, and the significance of such entanglements in the making of bioscience markets. Việt Nam offers a particularly interesting case through which to consider the networking ways through which biomedical economic formations come into existence.

A latecomer into the game of competitive biotechnology compared to Asia's so called 'biotech giants' – such as China and Singapore - Việt Nam has been overlooked in relevant literature (Walberg 2009:241). Though stem cell science is still in its infancy, there is a flurry of pertinent entrepreneurial activity in this market socialist country. Such economic activity is generally facilitated by state-backed collaborative science projects implicating an array of institutional actors including national universities, public and private hospitals, health departments, scientific committees and biotech firms. The stated aim of such 'national science projects', as they are called in Viet Nam, is to develop stem cell products for the market and build viable biomedical businesses. Developing stem cell applications that can be

easily put into commercial uses is an official policy priority, and an entrepreneurial approach to bioscience research, is a disposition carefully cultivated in Vietnamese state-funded universities and public hospitals. This prioritization of commercial uses and applicability is further pursued in official policy by means of directing stem cell research away from highly innovative and often controversial practices – that many Vietnamese experts associate with China - and towards replicating technologies that have long been tested and approved in Euro-American contexts, with the view to making such technologies available to patients at much lower prices. A case in point, is a recent ‘national science’ award made to a public university laboratory to fund a field trip to stem cell centres in Europe in order to identify methods that could be easily ‘transferred’ to Việt Nam, as a leading scientist at the laboratory put it.

State involvement in economic life bespeaks as much of Việt Nam’s particularities as a market-oriented socialist country, as of general trends in the development of biotechnology industries.<sup>1</sup> The ethnographic case presented here allows studying not only the crucial role of public private network partnerships in developing biomedical industries, but most importantly studying the ways in which scientific pursuits, business concerns and official practices become inexorably enmeshed in market-making processes. In what follows, I trace collaborative efforts to conduct research and turn bio-matters into for-profit ventures.

The article is based on fieldwork conducted in 2014-15 in Việt Nam’s two main stem cell hubs, namely Hà Nội and Hồ Chí Minh City. Fieldwork allowed engaging with a range of actors involved in stem cell applications including university staff and students, laboratory researchers, medical practitioners, hospital administrators and biotech staff, as well as members of government-run committees regulating biomedical research. Circumstances in the field limited engagements with patients. In Việt Nam, patient organisations are scarce and

tightly controlled by the government and the prospect of my interacting with patients, let alone activists, was alarming to my informants. My declared scholarly interest on stem cell practises in Việt Nam was appreciated by informants, not least as holding promise for fostering links with academic communities abroad and bringing Vietnamese biomedical endeavours to international attention. Even so, efforts to gain research access to laboratories, hospitals and biotech firms were not without challenges. In several instances where informants granted research permission, they took the initiative of arranging group interviews by inviting their colleagues and associates to partake. This methodological imposition brought the collaborative engagements animating the formation of stem cell entrepreneurial networks into analytical focus.

### ***On bioscience markets***

The complex relationship between bioscience and economic processes has been a central concern in the social study of biotechnology (Rose 2001; Waldby 2002; Waldby & Mitchell 2006; Rajan 2006; Cooper 2008a). This relationship is often described by employing an array of 'bio-concepts' (Birch & Tyfield 2012:300), such as 'bioeconomics' (Rose 2001), 'biovalue' (Waldby 2002) and 'biocapital' (Rajan 2006). For instance, writing on the rapidly expanding economies of exchange in human tissue in Britain and the United States, Waldby and Mitchell (2006) look at the technical manipulation and circulation of bodily fragments and their increasing enmeshment with processes of 'capitalisation' and market value creation, and elaborate a theory of 'biovalue'. 'Biovalue', a term introduced in earlier work by Waldby (2002:313), is defined as the (re)generative and productive capacities of living entities that can be 'instrumentalised' so as to become useful to human science and market projects. Further writings elaborate on theories of bioeconomy that conceptualise biological

substances as highly productive resources that can be manipulated to yield a 'surplus' of both life and economic value (Cooper 2008a; Rajan 2006). Such studies advance understandings of science development and its relation to political economy by reflecting on the production of new organic forms and life-enhancing technologies and the ways in which such forms might be invested with moral and economic values and enter gift or commodity circuits, and the ethical and social issues arising thereupon. However, reflections on life science matters and how these could become calculable commodities (or not) is predicated on an assumption of biological substances as highly productive resources endowed with inherent vital properties, on the basis of which social processes of valorisation and calculation proceed. Biological substances are thought as imbued with animating qualities that can be processed to produce both improved health and economic development. Therefore, paradoxically, the analyses of the social production of bioscience and markets is premised on a given, pre-existing 'biological'. Such epistemological premises, which have implications for the analysis of science and markets, have been criticised in an array of seminal anthropological and sociological writings that challenge taken-for-granted understandings of both 'nature' and 'society' (Viveiros De Castro 1998; Ingold 2000; Latour 2005). As Latour (2005) and other actor-network-theory scholars suggest what is 'nature' and what is 'society' cannot be taken for granted but instead should be the very object of sociological enquiry.

In reworking a theory of biovalue, a set of further studies shifts attention from biological specimens to their reformulation as information, suggesting that it is information on bio-matters and their therapeutic potential that fuels the capitalisation of human tissue and business investment on biotechnology (Novas 2006; Martin et al 2008; Petersen et al 2011). Considering the role of media representations, public and scientific discourses in raising patients' expectations for medical breakthroughs, these studies point to hyped

‘regimes of hope’ as forming the basis of commodity value and the emergence of ‘promissory bioeconomies’ (Martin et al 2008: 127).

Promissory discourses and speculative narratives on future economic value have become key conceptual elements in the social analysis of biotechnology markets. This scholarly emphasis on narratives and future potentialities is perhaps not surprising given the radical uncertainty manifest in the practice of bioscience. In the stem cell field, this uncertainty arises from largely experimental practices, difficult-to-prove results and the manifold risks to human health and entrepreneurial undertakings entailed therein. Presently, only a handful of stem cell applications have been clinically proven to be safe and effective in treating diseases, and even in this case it is widely acknowledged that long-term health effects remain unknown. And so, speculation is vital in the process of creating life science capitalist formations as Cooper (2008a) astutely observes. Yet, speculation is important for understanding bioscience markets if we are to study speculation as a practice – an effort to raise profit on the promise of surplus value - rather than as pertaining to abstract thought. Beyond exercises in speculation, the making of biomedical commodities and markets involves an array of scientific, official and entrepreneurial practices that remain understudied.

Reflections on bioeconomy throw ample light on the economic imaginaries entailed in the development of life sciences and the rationalities underpinning bioscience capitalist formations. However, as Cooper and Waldby (2014) suggest this scholarly emphasis on vision and speculative discourses should not come at the expense of studying the work involved in the capitalisation of life sciences. Cooper and Waldby (2014) call attention to the unacknowledged ‘clinical labour’ performed by patients and donors by means of giving samples to biobanks and taking part in biomedical experiments, pointing out that this visceral and risky labour, which is often performed by socially marginalised and uninsured patients, is

critical for understanding biomedical modes of production. Producing stem cell products is indeed a painstaking and labour-intensive process implicating a diversity of actors and a series of transformative sequences: from knowledge instilled in science students in universities and advanced by researchers in laboratories to micro-parts extracted from humans bodies and subsequently isolated into identifiable parts that are induced to proliferated in test rooms before being transplanted into patients whose health condition is monitored in the context of clinical trials, the results of which are translated into scientific evidence submitted to scientific committees to be considered for approval as patented stem cell products for the healthcare marketplace. The ethnographic exploration into Vietnamese stem cell ventures presented here casts further light into aspects of this laborious process by considering the expert clinical practices, entrepreneurial undertakings and official procedures involved in setting up clinical experiments and translating results into commercial ventures.

This ethnographic exploration into makings of stem cell enterprise draws on network-based approaches to the study of technoscience that allow for practice-focused research and an appreciation of the complex social interactions through which markets come be constituted (Latour 1983; Callon 1986; Sleeboom-Faulkner 2011, 2014). Callon's (2007) understanding of markets as 'performative' rather naturally occurring phenomena based on innate human tendencies serves as a particularly inspirational resource here. Callon (1986) suggests that new economic spaces and markets are created by means of configuring complex networks implicating a heterogeneity of actors, including human and non-human ones, such as microorganisms, theories, policies and devices, as well as the careful arrangement of relations between these actors. Engaging with such insights the article examines stem cell markets as socially constituted, paying particular attention to the collaborative engagements that allow configuring bio-matters into detachable and identifiable entities with 'objectified'



properties that can be turned into calculable objects to be transacted (Callon & Muniesa 2005). The actors involved in Vietnamese biomedical entrepreneurial networks – be it human subjects, policy documents or bodily fragments - are not considered here as having fixed traits and pre-existing agendas. Rather the emphasis is placed on transfigurations and how actors are being continuously (trans)formed by means of taking active part in assembling biomedical networks. Two ethnographic instances discussed later here illustrate the point, namely that of a trainee doctor turned bioentrepreneur and a newly-founded biotech firm. Both emerge as entrepreneurial actors through their involvement in collaborative stem cell clinical research projects.

This empirically grounded study of stem cell entrepreneurial networks in Việt Nam engages with calls for embedded understandings of markets that anthropologists and political economy thinkers have repeatedly articulated (Polanyi 1944; Granovetter 1985; Hefner 1998; Callon & Muniesa 2005; Smart & Smart 2005). Hefner's edited volume *Market Cultures* (1998:2) as well as writings on *Petty Capitalists* (Smart and Smart 2005) reiterate the need for more sociologically realistic and empirical inquiries into economic life. Ethnographically grounded studies of capitalist markets do not merely add to the ethnographic record and comparative analysis by exploring the variable articulation of capitalist formations, but further allow obviating abstract understandings of economic life as well as the risk of repeating essentialising generalisations about science, nature and the social more generally.

### ***Stem cell networks***

Stem cell research and applications is a rapidly growing field in Việt Nam. In the past decade, stem cell science and its profit-making potential have attracted considerable interest, with an

array of public and private bodies joining in biomedical research projects geared towards developing commercial applications. Recent market reforms and sweeping changes in healthcare policy have created the conditions for scoping stem cell science as a 'new profitable business in Việt Nam' and assembling biomedical networks (VietnamNet 2013).

The set of 'renovation' policies known as *đổi mới* introduced by the socialist state in 1986 ushered in economic transformation signalling a move from a centrally planned to a market-oriented economy. Still ongoing, such reforms had a profound impact on the health sector changing how healthcare is delivered, managed and funded. Since 1989, a series of policies have sought to decentralise, deregulate and open up the health sector to market forces, by means of legalising private medical practice, privatising pharmaceutical production and sales, imposing charges in public hospitals, and introducing state-funded and voluntary health insurance schemes (Chen & Hiebert 1994; Ladinsky 2000; Tran et al 2011; Kerstin 2012). The introduction of 'user fees' in public hospitals was a significant step towards creating for-profit opportunities in healthcare. In recent years, the Vietnamese state has transferred responsibility to public hospitals for raising and managing their own funds granting them greater 'autonomy' (Tran et al 2011). In this context, public hospitals are becoming increasingly oriented towards the provision of cutting-edge expensive biomedical technologies as a way to boost their income.

Public hospitals are at the forefront of experimentation with both stem cells and biomedical entrepreneurial projects. Stem cell applications are mainly undertaken in hospitals run by the state or army.<sup>2</sup> National haematology units are a case in point, making the most out of readily available blood resources, which can be used to harvest stem cells, to build commercial stem cell treatment and storage services. A telling case is the Haematology hospital in Hồ Chí Minh City, which pioneered the first stem cell transplant in the country

(1995) using bone marrow cells to treat a blood-cancer patient. Since then, it has ‘successfully carry out hundreds of transplants’, according to past and current directors (Tran Van Be *et al* 2008:146). Today, the hospital is poised to launch a commercial stem cell bank alongside its national blood storage services, fostering ambitions to trade in stem cells with foreign partners in Europe and beyond.

Since the first stem cell transplant in 1995, a series of public hospitals have seized upon stem cells as a potentially lucrative pursuit, especially in Hồ Chí Minh City. Since 2004, state and army-run hospitals in Hà Nội have been busy setting up stem cell units, building capacity and expertise by teaming up with basic researchers in public university laboratories and biotech companies to conduct research, and translate findings into scientifically proven ‘therapies’ that could be subsequently considered by government-sponsored science committees for commercial license.

Such collaborative research projects are conducted under the auspices of ministries as ‘national science projects’ (*Đề tài nghiên cứu khoa học cấp nhà nước*). Stem cell projects are mainly supported by the Ministry of Health that oversee all relevant undertakings, issuing permissions for basic and clinical research and running scientific and ethics committees that assess research proposals and findings.<sup>3</sup> National stem cell projects are allocated some funds from government coffers, but such funding is ‘limited’ and ‘insufficient’ for covering the substantial costs involved, as Vietnamese scientists and policy makers remarked. To fill the funding gap in national projects, official policy actively encourages private interests to invest and work with state-run and public institutions in order to develop commercial applications.

Science regulatory policy seeks to expand stem cell networks further and increase their chances in yielding commercially viable results. Like elsewhere in Asia, the Vietnamese government takes an economic - if not ‘permissive’ (Isasi & Knoppers 2006) - approach to

regulation, governing bioscience through minimal rules and 'soft law' and a near-absence of policy implementation instruments.<sup>4</sup> In this regulatory environment, state-sponsored science committees become an important node in stem cell enterprising networks contributing to stem cell product development through processing research licenses and commercial approvals (see later here).

National projects seek to animate market forces in yet more ways. National schemes support research that is 'applicable' and has good commercial prospects, as a chief laboratory scientist commented. The commercial potential of stem cell applications is top in the agenda of health officials and a key criterion for approving research licenses and funding. To expedite the pathway to market and secure state support Vietnamese basic and clinical researchers employ stem cell techniques that have long been tested and applied, especially in 'Western contexts' (miền Tây). In the words of a chief scientist in a stem cell laboratory, 'in Việt Nam we use simple techniques, like autologous transplants and hematopoietic stem cells that carry fewer complication risks' (see also Van Be et al 2008:146). For similar reasons, mesenchymal stem cells, which are widely reported to have many potential applications, are becoming the mainstay of biomedical practice in Viet Nam.

Despite claims by doctors and laboratory scientists, the effects and risks of stem cell applications in Việt Nam - much like elsewhere in the world - remain largely unknown. Regular reports in the state-controlled Vietnamese press entertain public perceptions about the cost and effects of stem cell applications, portraying clinical experiments as life-saving 'treatments' offered to patients 'free of charge' in public hospitals. However, to date there are no stem cell 'therapies' officially approved to be safe and effective, and any future treatments will only be accessible to wealthy paying or privately insured customers, as indicated by doctors and biotech staff I conversed with.

Such admissions did not deter my interlocutors' efforts to develop stem cell applications. At the time of my fieldwork, a number of research projects were underway, notably 'clinical trials' (*thử nghiệm lâm sàng*) conducted in hospitals in Hà Nội and Hồ Chí Minh City. These clinical studies provided the means not only for exploring the remedial benefits and safety of stem cell applications but further for launching an array of for-profit stem cell ventures, as demonstrated in the following two sections.

### ***Clinical trials and the making of bio-entrepreneurs***

A number of clinical studies recorded during fieldwork experimented with autologous stem cell transplants for the treatment of knee osteoarthritis and spinal cord injuries, conditions that affect many in Việt Nam (Fan 2012). The focus of attention here is a 'clinical trial' (*thử nghiệm lâm sàng*) assessing the effects of adipose tissue extracted stem cells for the treatment of spinal injuries. The 'trial' was conducted in a major public hospital in Hà Nội - I will call it *Thân*.<sup>5</sup> Founded by the French colonial administration the hospital is still one of the country's major medical units. The study was a 'national project' conducted under the auspices of two government ministries and sponsored by a newly-founded biotech firm. The biotech and its collaborative engagements with the hospital are discussed in the next section. This section focusses on the professional activities of the medical team leading the spinal cord study, and a young doctor in particular. I will call this young doctor *Doanh*, as in *doanh nhân* that means 'businessman', a most fitting pseudonym as it transpires. The unfolding of Doanh's educational and professional career trajectories allows for tracing the ways through which young doctors acquire stem cell expertise and come to engage in biomedical business.

*I am a spinal surgeon. In Việt Nam we have many road and work-related accidents that result in spinal cord injuries, and my hospital has the largest influx of such patients in the country. There is a swelling demand for relevant medical services and great potential there...*

Some of the words with which Doanh introduced himself when we met in a hotel lobby. Dressed in a smart blue suit, akin to Vietnamese business folk, he chatted on his smartphone to his 'big boss', finalising details for my research visit to the hospital in order to meet the rest of the spinal cord study team. The 'big boss' was Doanh's academic supervisor – or 'mentor' as Doanh referred to him - and the director of the hospital's orthopaedics ward where the trial took place. Doanh was one of two doctors leading the study as 'co-principal investigators' (co-PI). At the time, Doanh was completing his graduate medical education, doing a PhD in a national medical university. As part of his PhD, Doanh was doing in-service training at Thân hospital's orthopaedics unit. Like most major public hospitals in Việt Nam, Thân is a university hospital, serving as a trusted surgical unit as well as a training facility for medical students. Born to a family of doctors - his father a medical university professor and his mother practising 'traditional medicine' – Doanh was one of few students fortunate to gain access to this highly competitive residency training scheme. Acting as co-PI in the study was integral part of his residency training. Through Doanh was a co- PI in the 'trial' he was not authorised to carry out stem cells interventions on participating patients. A more senior doctor with several years of medical professional 'experience' and service at the very hospital performed all stem cell procedures, while the director of the orthopaedics ward oversaw and authorised all procedures. Nonetheless, the study allowed Doanh to build expertise in using stem cells on patients with orthopaedic conditions.

The three-year spinal cord study was officially the first stem cell project at Thân hospital. It was conducted in a sparkling new tower-building where the orthopaedics ward had recently

relocated. By way of initiating me to the 'trial', Doanh gave me a tour around the orthopaedics ward pointing to participating patients and explaining their condition and stem cell treatment. First there was a girl in her twenties with a 'very serious condition affecting her movement and bodily functions', Doanh explained. Pointing to her abdomen, Doanh explained that a tissue sample had just been extracted and was on its way to the laboratory to isolate and process stem cells in order to inject back to the young patient as part of the trial. Next, Doanh pointed to a young man suffering partial paralysis after falling from a height in a construction site, and then a middle-aged family man affected by a similar condition. Stressing the graveness of patients' conditions, Doanh cautiously pointed to 'improvements' since the start of the 'trial'. Such improvements were, however, only slight relating mostly to patients' 'quality of life', such as the ability to control urination, as Dr Triệu, the other co-PI at the trial and senior doctor who carried out stem cell interventions on patients, explained. Dressed in a white coat, Dr Triệu took the lead in answering my questions about the 'trial' in a group interview that Doanh had organised and included staff from the biotech firm sponsoring the 'trial' (see next section). Voicing a cautious approach to promissory narratives, Dr Triệu pointed out that despite best efforts by the medical and biotech team to extract, proliferate and carefully plan and administer stem cell transplants, there were no significant improvements in the patients' condition in the course of this study. In his words:

*The trial has been running for three years and concludes in a few months but it has not produced any positive results. We used stem cells to treat acute spinal cord injury but we cannot claim significant improvements in the patients' condition... Participating patients were selected on the basis of their level of injury; they are people with acute spinal cord trauma who do not have complete paralysis. They also have little to lose. The patients had stem cells transplants applied six months after surgery. Their chances in recovery are very low. They might get better, but it is not likely that this will be due to stem cells.*

This 'trial' may have failed to produce positive remedial results, but turned out to be productive in other regards, allowing a number of actors involved to launch further research and entrepreneurial projects. Firstly, inconclusive clinical results provided the basis for the hospital applying and securing further ministerial support for a new national 'clinical trial' on spinal cord injury. The study would be led by the same two doctors, thus allowing them to build pertinent expertise. The new trial - which was regarded by medical and biotech staff involved as a 'continuation' of the first - would also enable the hospital to build stem cell capacity with the view to offering pertinent services to paying customers in the near future. The same biotech firm would sponsor the second 'spinal cord trial' as well as further stem cell studies due to start at the hospital the year after. Sponsoring projects in a major public hospital effectively allowed the biotech to build a stem cell business, as explained in the next section. Finally, Doanh emerged out of this inconclusive clinical study as a stem cell specialist and a budding bioentrepreneur. In subsequent interviews, Doanh spoke about plans to formally launch a private company offering a range of medical services, including stem-cell related ones, as soon as the ongoing trial and thus effectively his PhD training concluded.

At the time of my fieldwork, Doanh and his business partner - a man in his late twenties with a Master's in economics and experience in selling medical supplies - were in the process of launching a private medical services company, and stem cells were at the core of their business model. The company had three divisions: a web-based information network on stem cell treatments and practitioners available in Việt Nam; a private clinic specialising in orthopaedics treatments including stem cell-based ones, and a stem-cell-related product distribution network.

The website was already running at the time of my fieldwork. It provided information on stem cell treatments and specialists in Việt Nam to patients wishing to 'buy treatments



and healthcare services' through a log-in system, Doanh's partner explained. This log-in service collects data on patients', hence creating a database that can be then sold to clinics and medical professionals, he added. In a group interview with the two business partners, Doanh excitedly revealed that he had just secured official licence to open the private clinic. Doanh explained that the clinic would have twenty members of staff including four doctors and a dedicated stem cell unit. Doanh was also looking to capitalise on the stem cell expertise gained through his residency training by providing consultancy on stem cell trials and treatments to other hospitals. In his words:

*After I finish my PhD I want to advise hospitals on how to conduct stem cell clinical trials and build dedicated units. I am currently involved in more than one national projects on stem cells and there are many hospitals, both private and public, looking to provide stem cell services.*

Apart from the private clinic and website, the two partners were also setting up a distribution network providing stem-cell-related products, like 'extraction kits' and machinery for processing tissue, to hospitals and clinics around Hà Nội. Through all these means, the two partners sought to make the most of a growing demand for stem cell services in Việt Nam, driven mainly by wealthy Vietnamese and health tourists from abroad. As Doanh put it:

*Rich Vietnamese currently travel to South Korea and Japan for stem cell procedures, both therapeutic and health-enhancing treatments. We want to keep them here. We also want to attract health tourists, especially Việt Kiều (overseas Vietnamese) from the USA, who could come to Việt Nam for stem cell treatments that are good but much cheaper than the US or Europe. We want their dollars.*

The young medical practitioner, Doanh, was not the only one to emerge out of involvement in 'clinical trials' as a budding bio-entrepreneur. A 'biotech company' (*công ty công nghệ sinh học*) came to build their stem cell trade through participation in the spinal cord study and

other national stem cell research projects conducted in a major public hospital, as illustrated in the next section. I will call this biotech *Nhìn Xa*, which translates as ‘visionaries’.

### ***Stem cell ventures***

*Nhìn Xa biotech* was formally launched a few months before the first stem cell ‘trial’ at Thân hospital started. The company was founded with this very purpose as stated on their website: to isolate, culture and supply stem cells to Thân hospital. The company’s formal opening (*lễ khai trương*) was marked by the ceremonious signing of a ‘cooperation agreement’ with the hospital. It was at this very hospital I first came to know about the biotech as a ‘sponsor’ to the spinal cord ‘clinical trial’ and met some of the company’s staff. The biotech staff tasked with liaising with Thân hospital over the spinal cord and other stem cell studies were four women and men in their mid- to late twenties who had flocked to the capital from other provinces to forge a career in science-based business upon finishing a Master’s degree in biotechnology.

The spinal cord study is not the only stem cell project over which *Nhìn Xa biotech* and Thân hospital collaborated. The company sponsored two further ‘clinical trials’ at the orthopaedics ward due to start soon after the ongoing spinal cord trial concluded. One of these new trials was a continuation of the ongoing spinal cord study, while the other was on ‘degenerative joint disease’. Further trials relating to various diseases were also to start around the same time in different wards at the hospital, notably a project on ‘liver disease’. All three aforementioned ‘trials’ were ‘national projects’ supported by ministries. Apart from ‘clinical ‘trials’, the biotech is working with the hospital in carrying out small scale stem cell experiments concerning ‘rare degenerative conditions for which very little is known’, as Xuân,

one of the female biotech staff noted. These ‘are not clinical trials as they involve only one or two patients’, Xuân explained. Moreover, Xuân added, in these cases ‘patients pay for their treatment’ unlike clinical trials that are ‘free of charge’ for patients and the ‘sponsor covers all relevant expenses’. These informal try-outs initiated at the ‘patients’ request’, as well as formal ‘trials’, are often noted in the biotech’s brochures as ‘treatments’. Such promotional acts may or may not be indicative of future-bound attitudes to biomedicine but what is certain is that they affect in significant ways current stem cell practices in Viet Nam by blurring the boundaries between experiments and therapies.<sup>6</sup>

According to their website, Nhìn Xa is the ‘first company [in Việt Nam] licensed by the Ministry of Health to culture and supply stem cells derived from adipose fat tissue’. Cuong the biotech’s young male R&D manager explained, ‘we can extract many different kinds of stem cells from adipose tissue, but we are interested in isolating and storing mesenchymal stem cells, as these have a diversity of possible applications for the treatment of a host of diseases’. Giving me tour around the biotech’s laboratory and storage facilities, Cuong explained about the biotech’s work and contribution to stem cell studies at Than hospital:

*We obtain tissue that is extracted from patients treated at the hospital as part of clinical studies. After we extract the stem cells from the tissue we induce them to proliferate and we divide them so as to prepare a number of injections needed for the treatment of patients. Between injections we need to store stem cells, so, we also operate a stem cell bank. After the treatment [as part of the trial] concludes, we store the remaining stem cells for one year free of charge. Then, if the patients wish to continue storing them they pay an annual fee. Patients might need to use stem cells again for future applications. Healthy patients can also make [stem cells] injections to improve their general health. [Apart from the spinal cord study], we are looking to develop stem cell applications for a series of diseases as well as for cosmetic purposes.<sup>7</sup>*

Involvement in national projects in a public hospital is of crucial importance for the biotech’s fledgling business, allowing them to transform experiments with human bio-matters into a

range of commercial services. By means of sponsoring clinical studies, the biotech gains access to human tissue that is subsequently modified to form their main commodity, namely stem cells. This allows the biotech to kick start a stem cell storage service, by enlisting trial patients with the view to turning them to customers willing to pay for storing their samples for future applications after the conclusion of the trial.

Another way through which the biotech seeks to build a stem cell business is by enlisting institutional clients and selling their expertise gained through the trial, as well as the intellectual property rights on the resulting technology to other organisations. Hospitals constitute one category of possible clientele, insurance companies another. In the words of Xuân,

*After the spinal cord study concludes and is approved by the ministry [of Health] as a therapy the company will transfer the patented technology to other hospitals e.g. we will show them the specific methodology and train their doctors on how to apply it.*

The issue of who owned clinical results and methodologies was rather unclear with often conflicting views voiced during conversations and interviews depending on the interlocutor's job and affiliate institution, thus pointing to many stakeholders. Biotech staff were cautious about making claims, saying that clinical results from the spinal cord study 'belong to Than hospital'. But by acting as 'sponsors' to clinical studies and as evident from their business plans, the biotech staked a claim on resulting stem cell technologies. 'Collaborating with insurance companies' was another way the biotech sought to create a space for profitable transactions. Loan, one of the female employees, explained:

*At the moment, national insurance does not cover stem cell procedures, and neither do insurance companies. If the spinal cord treatment is approved by the Ministry of Health then insurance companies will be able to add it in their list [of therapies]*

*covered], and hence gain a competitive advantage over other insurance companies. This is an opportunity for us to work with insurance companies and invite investment.*

Realising the economic potential of stem cell applications and turning profits out of uncertain investments hinges on transforming ‘clinical trials’ into scientifically tested and officially approved ‘therapies’ that can become commercially available. Government bodies and state agencies play a crucial role in this process of translation.

### ***From trial to therapy***

Health policy instruments, ministry-led science schemes and public bodies are important nodes in stem cell networks allowing research to take place and entrepreneurial undertakings to materialise. To begin with, most basic and clinical studies recorded during fieldwork were national projects conducted under the aegis of government ministries. Such projects allow assembling stem cell networks that bring together a number of disparate actors such as scientists working in national universities and laboratories, practitioners in public and private hospitals, local health officials, biotech staff and patients as well as biomaterial, scientific data, hi-tech equipment and facilities. Public bodies’ involvement and ministerial support allows not only gathering a diversity of human and non-human actors as well as the resources required for biomedical research but further facilitates the process of obtaining required research permissions and commercial biomedical licenses. Such licensing procedures allow to effectively transform biomedical research and clinical data into certified stem cell products for the healthcare market.

Licensing and quality controls in biomedicine, and healthcare in general, are reported to be poor and undeveloped in Việt Nam (Tran et al 2011). However, several licensing

applications for certifying stem cell technologies as safe and effective for the healthcare market were in progress during my fieldwork, and some of them secured approval. Official licensing procedures support the development of stem cell commodities in every step of this long process, not least by means of enabling a series of transformations. To start with, a license is required to engage in basic research with such licenses granted only to studies taking place or involving the participation of public universities. Basic research results form the basis for securing a license for the next main stage in stem cell research which is clinical experiments with animals. The results of ‘animal model’ research can be used to apply for official permission to conduct ‘clinical trials’ involving patients. The involvement of public hospitals is again crucial here. The case of a private clinic that partnered up with an army-run hospital with no stem cell expertise and appropriate amenities by way of acquiring approval to conduct ‘trials’ illustrates the point. Crucially, official approvals are essential for translating often tentative stem cell clinical experiments with patients into officially certified commodities that can be transacted. Talking about the spinal cord study Loan at the biotech explained:

*The state [nhà nước] has to decide if the therapy is safe and efficient. The ministry of health is vetting the whole process, running checks on participating scientists and doctors and making sure we follow correct procedures and abide with laws and regulations. After we complete the trial, we report the results to the ministry (báo cáo nghiên cứu). We have to wait for the ministry to assess trial results, which can take up to two or three years of meetings upon meeting, which is a long time for patients to wait.*

There is a lengthy, multi-step process involved in responsibly translating science and research into safe and effective treatments (Salter 2008). By way of explaining the process in Việt Nam my interlocutors at Nhìn Xa biotech counted the main steps involved. After the ‘trial’ concludes, the hospital and biotech team that led the project report to the hospital’s

orthopaedics ward management, which in turn considers results and subsequently reports higher up the rank to the hospital's 'science council'. The council will then formally report trial results to the Health Ministry's 'Bureau of Administration for clinical trials' (*Cục quản lý thử nghiệm lâm sàng, Bộ Y Tế*). 'This bureau will decide whether this method is good for the patients or not, whether it is safe (*an toàn*) and effective (*hiệu quả*)', as Xuân at the biotech put it.

To increase their chances in procuring official permissions and approvals that would allow turning trial results into marketable commodities the two partners, Thân hospital and Nhìn Xa biotech, collaborated with a number of state-run institutions. Specifically, the spinal cord study involved cooperation with two other public hospitals for the purposes of 'aiding patients' recovery' and 'verifying clinical results', Xuân explained. A 'national' hospital provided trial patients physiotherapy sessions, especially those who had problems controlling urination, and monitored overall progress in their condition through 'somatosensory' muscle-related and MRI tests. An army-run hospital also run regular checks on clinical trial data to identify possible improvements in the patients' condition.

In market socialist Việt Nam, state involvement in stem cell ventures is regarded with ambivalence by scientists, doctors and experts in public and private institutions partaking in national projects. Many protest that protracted 'bureaucratic procedures' and burdensome 'ethical requirements' often encumber biomedical projects by adding to workload and delays. Yet, government schemes and public body participation allow stem cell projects and potentially profitable outcomes to materialise, thus playing a vital role in turning the promise of stem cell science, and often unpromising research results, into vetted 'therapies'. Through these means Vietnamese state apparatuses and official practice help carve out new spaces for market transactions.

### ***Conclusion***

The global rise of bio-industries has in recent years captured the attention of anthropologists and science studies scholars often serving as a vehicle for analysing contemporary capitalism and its changing trajectories. Bioscience is thought by many scholars as well as policy makers as a perfect example of a 'new economy' that could be a major driver for social and economic development. Life sciences, with its potential to create new organic forms that can prove to be productive and beneficial in number of ways, has become a field for sprawling speculative activity and investment. In Việt Nam, efforts to encourage economic activity in the field of stem cells and build a biomedical industry are ongoing and intensifying.

Despite burgeoning entrepreneurial activity in the field of stem cells in Việt Nam and elsewhere in the world, stem cell undertakings are beset by a number of fundamental uncertainties. Stem cell science and applications are still largely experimental and potential benefits regarding human health, often advocated by scientists and policy makers, are yet to be substantiated.<sup>8</sup> On that basis, it is difficult to consider stem cells and related bio-matters as given and naturally productive sources of vitality and wellbeing that can produce health and financial gains. Rather how body micro-parts come to be engineered into identifiable organic forms with potentially life-giving properties, on the basis of which they are constituted as valuable commodities to be transacted should be very object of social enquiries. The ethnographic case presented here illustrates that in market socialist Viet Nam, state-backed clinical research serves as a primary means for developing commercial applications and ventures in biomedicine. Such experimental processes do not merely assess the therapeutic potential of stem cell applications on patients but also engineer biomedical



technologies and entrepreneurial actors. Government-supported experiments and licensing procedures allow developing marketable stem cell applications despite inconclusive clinical data and uncertain results. Looking into how clinical experiments are organised and conducted in Việt Nam allowed tracing the entanglements of stem cell science, entrepreneurial undertakings and official practice, and the significance of these entanglements for understanding emerging biomedical industries. Through these means, this ethnographic exploration into the makings of Vietnamese stem entrepreneurial networks hopes to add to empirical inquiries on the social constitution of markets.

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<sup>1</sup> Ong and Chen's (2010) volume point to a general trend towards 'state entrepreneurialism' in creating effervescent bioscience economic activity. Rajan (2006) also notes that state policy and funding have played a key role in the development of bio-industries in the United States.

<sup>2</sup> Some of the hospitals involved in stem cell applications are the Paediatric Institute, Bach Mai Hospital, Blood transfusion and Haematology Institute, 103 and 108 Military Hospitals in Hà Nội, and the Blood Transfusion and Haematology Hospital and 115 People's Hospital in Ho Chi Minh City.

<sup>3</sup> The Ministry of Science and Technology also sponsors stem cell studies.

<sup>4</sup> The first regulations on clinical research were introduced between 1996 and 2002. In 2007, the Health Ministry laid out a plan to introduce further regulations and guidelines for good practice. However, by official admission, the regulatory framework remains 'weak' (see MoH Report 2009).

<sup>5</sup> As in thân hình (body). All names used in this article are pseudonyms.

<sup>6</sup> We also need to allow for culturally specific medical understandings and practices, which however fall beyond the scope of the article.

<sup>7</sup> To date using stem cells for cosmetic purposes is banned in Viet Nam, but several private clinics advertise such services.

<sup>8</sup> This uncertainty about the safety and efficiency of stem cell applications applies unevenly in different sociotechnical settings around the world, nevertheless it persists as a general condition.